

### **Remarks**

Claims 1-39 and 41-46 were pending in the application. Claims 19, 21, and 41-43 are amended herein. Claims 20, 29, and 30 are hereby canceled without prejudice. No new matter is added. Therefore, after entry of this Amendment, **claims 1-19, 21-28, 31-39, and 41-46** are pending in this application. Consideration of the pending claims is requested.

### ***Election/Restriction***

Applicants thank the Examiner for rejoining and examining previously withdrawn claims 31-39.

### ***Claim Rejections – 35 U.S.C. § 112, first paragraph***

Claims 19-30 and 41-43 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. Applicants traverse, to the extent the rejections are maintained after entry of the amendments made herewith.

The Office asserts that claims 19-30 and 41-43 lack enablement because it would require “an exhaustive search for which diseases can be treated by which compound of claim 1...” (Office action, page 6, third full paragraph). In particular, the Office asserts that AIDS is a collection of many diseases, resulting from a lack of an effective immune system. Claims 19 and 41-43 are amended herein to recite a “method of treating HIV infection...” Reference to “AIDS” is deleted.

The test for enablement hinges on whether or not the specification teaches one of skill in the art how to make and use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988); *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1365 (Fed.Cir.1997). Lack of enablement arises where the specification requires one of ordinary skill in the art to perform “undue experimentation” to practice the invention as broadly as it is claimed. *In re Wands*, 858 F.2d at 737. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *Id.* In fact, a considerable amount of experimentation is permissible, if it is merely routine or if the

specification provides a reasonable amount of guidance in which direction the experimentation should proceed. *Id.* citing *In re Angstadt*, 537 F.2d 489, 502-504 (CCPA 1976).

The specification clearly demonstrates that the disclosed compounds are inhibitors of HIV integrase (Example 4, pages 53-57). The specification also demonstrates that the disclosed compounds have antiviral activity, as evidenced by their antiviral activity in HIV-1-infected cells (Example 5, pages 57-58). The specification also describes modes of administration of the disclosed compounds and pharmaceutical compositions (*e.g.*, page 18, lines 17-26 and page 21, line 25 to page 22, line 2) and suitable dosage ranges for treating HIV infection (*e.g.*, page 19, lines 10-17 and page 23, line 23 to page 24, line 17). Based on the teachings of the specification, one of ordinary skill in the art could administer the disclosed compounds to subjects with HIV infection and determine the efficacy of the compounds in treating the infection (for example, by monitoring HIV viral load or CD4<sup>+</sup> cell count) utilizing only routine experimentation. An example of such studies utilizing an HIV integrase inhibitor is DeJesus *et al.*, *J. Acquir. Immune Defic. Syndr.* 43:1-5, 2006.

In view of the teachings of the specification and the knowledge of one of skill in the art, it would not require undue experimentation to make and use the methods of claims 19-30 and 41-43 as amended herein. Therefore, withdrawal of this rejection is respectfully requested.

Claims 19-30 and 41-43 are also rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement for “preventing” diseases. Claims 19, 21, and 41-43 are amended herein to delete reference to *preventing* AIDS or HIV infection. Furthermore, claim 21 is amended to recite “wherein the method of treatment helps to delay progression of infection by HIV.” Support for this amendment may be found in the specification, for example, at page 17, lines 14-17. Withdrawal of this rejection is respectfully requested.

**Conclusion**

Applicants respectfully submit that the claims are now in condition for allowance. If any issues remain, the Examiner is requested to contact the undersigned to arrange a telephonic interview prior to the preparation of any further written action.

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